Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 28, 2001.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 02-2671 Filed 2-4-02; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF THE INTERIOR

National Park Service

Concessions Management Advisory Board Meeting

AGENCY: National Park Service, Interior.

ACTION: Notice of meeting of Concessions Management Advisory Board.

SUMMARY: In accordance with the Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 770, 5 U.S.C. App 1, section 10), notice is hereby given that the Concessions Management Advisory Board will hold its next meeting February 27 and 28, 2002 in Washington, DC. The meeting will be held at the Melrose Hotel located at 2430 Pennsylvania Avenue, NW, Washington, DC. The meeting will convene from 8:30 a.m. until 5 p.m. daily.

SUPPLEMENTARY INFORMATION: The Advisory Board was established by Title IV, Section 409 of the National Park Omnibus Management Act of 1998, November 13, 1998 (Public Law 105-391). The purpose of the Board is to advise the Secretary and the National Park Service on matters relating to management of concessions in the National Park System.

The Advisory Board will consider procedural matters and will be briefed and hold discussions on the proposed (Category III) simplified concession contracting procedures. The Board will also discuss its organizational and administrative procedures.

The meeting will be open to the public, however, facilities and space for accommodating members of the public are limited, and persons will be accommodated on a first-come-first-served basis.

Assistance to Individuals With Disabilities at the Public Meeting

The meeting site is accessible to individuals with disabilities. If you plan to attend and will need an auxiliary aid or service to participate in the meeting (*e.g.*, interpreting service, assistive listening device, or materials in an alternate format), notify the contact person listed in this notice at least 2 weeks before the scheduled meeting date. Attempts will be made to meet any request(s) we receive after that date, however, we may not be able to make the requested auxiliary aid or service available because of insufficient time to arrange for it.

Anyone may file with the Board a written statement concerning matters to be discussed. The Board may also permit attendees to address the Board, but may restrict the length of the presentations, as necessary to allow the Board to complete its agenda within the allotted time.

Interested persons may make oral/written presentations to the Advisory Board during the business meeting or file written statements. Such requests should be made to the Director, National Park Service, Attention: Manager, Concession Program, at least 7 days prior to the meeting. Further information concerning the meeting may be obtained from National Park Service, Concession Program, 1849 C Street NW, Room 7313, Washington, DC 20240, Telephone, 202/565-1210.

Draft minutes of the meeting will be available for public inspection approximately 6 weeks after the meeting, in room 7313, Main Interior Building, 1849 C Street, NW, Washington, DC.

Dated: January 22, 2002.

Fran P. Mainella,

Director, National Park Service.

[FR Doc. 02-2713 Filed 2-4-02; 8:45 am]

BILLING CODE 4310-70-P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 332-437]

Advice Concerning Possible Modifications to the U.S. Generalized System of Preferences with Respect to Certain Products Imported From AGOA Countries

AGENCY: United States International Trade Commission.

ACTION: Institution of investigation and scheduling of hearing.

SUMMARY: On January 17, 2002, the Commission received a request from the United States Trade Representative (USTR) for an investigation under section 332(g) of the Tariff Act of 1930 (19 U.S.C. 1332(g)) for the purpose of providing advice concerning possible modifications to the Generalized System of Preferences (GSP) with respect to certain products from beneficiary sub-Saharan African countries under the African Growth and Opportunity Act (AGOA). Following receipt of the request, the Commission instituted investigation No. 332-437, *Advice Concerning Possible Modifications to the U.S. Generalized System of Preferences with Respect to Certain Products Imported from AGOA Countries*, for the purpose of providing advice as follows:

(1) With respect to unwrought manganese flake as described by the USTR in its notice published in the **Federal Register** of January 24, 2002 (67 F.R. 3530), advice as to the probable economic effect on U.S. industries producing like or directly competitive articles and on consumers of the elimination of United States import duties only for countries designated as beneficiary sub-Saharan African countries under the African Growth and Opportunity Act (AGOA) in general note 16 of the Harmonized Tariff Schedule of the United States (HTS). The USTR requested that the Commission, in providing its advice, assume that the benefits of the GSP would continue to apply to imports that would be normally excluded from receiving such benefits by virtue of the competitive need limits specified in section 503(c)(2)(A) of the Trade Act of 1974 (1974 Act) (19 U.S.C. 2463(c)(2)(A)). The USTR noted that an exemption from the application of the competitive need limits for the beneficiary AGOA countries is provided for in section 503(c)(2)(D) of the 1974 Act (19 U.S.C. 2463(c)(2)(D); and

(2) With respect to prepared or preserved pears as described in HTS subheading 2008.40.00, advice as to the probable economic effect on United States industries producing like or directly competitive articles and on consumers of the removal of the article from eligibility for duty-free treatment under the GSP. The USTR noted that the article is currently eligible for GSP only for countries designated as beneficiary AGOA countries in general note 16 of the HTS. As requested by USTR, the Commission will seek to provide its advice not later than April 25, 2002.

EFFECTIVE DATES: January 29, 2002.

FOR FURTHER INFORMATION CONTACT: Project Manager, Douglas Newman (202-205-3328; *newman@usitc.gov*) in the Commission's Office of Industries. For information on legal aspects of the investigation contact William Gearhart of the Commission's Office of the

Determination of the Deputy Director for Program Management, CDC, pursuant to Public Law 92–463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to RFA OH–02–001.

FOR FURTHER INFORMATION CONTACT: Pervis Major, Ph.D., Scientific Review Administrator, National Institute for Occupational Safety and Health, CDC, 1095 Willowdale Road, M/S B228, telephone (304) 285–5979.

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: January 30, 2002.

Alvin Hall,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 02–2658 Filed 2–4–02; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01E–0097]

Determination of Regulatory Review Period for Purposes of Patent Extension; REFACTO

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for REFACTO and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human biological product.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Office of Regulatory Policy (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5645.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human biological product REFACTO (novel procoagulant proteins). REFACTO is indicated for the control and prevention of hemorrhagic episodes and for short-term routine and surgical prophylaxis in patients with hemophilia A. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for REFACTO (U.S. Patent No. 4,868,112) from the Genetics Institute, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 11, 2001, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of REFACTO represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for REFACTO is 1,751 days. Of this time, 987 days occurred during the testing phase of the regulatory review period, while 764 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* May 23, 1995. The applicant claims March 14, 1994, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 23, 1995, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* February 2, 1998. FDA has verified the applicant's claim that the product license application (PLA) for REFACTO (PLA 98–0137) was initially submitted on February 2, 1998.

3. *The date the application was approved:* March 6, 2000. FDA has verified the applicant's claim that PLA 98–0137 was approved on March 6, 2000.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,475 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (address above) written or electronic comments and ask for a redetermination by April 8, 2002. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 5, 2002. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch. Three copies of any information are to be submitted, except that individuals may submit one copy.